

REMARKS

Reconsideration of this application, as amended, is respectfully requested.

The July 31, 2002 Office Action and the Examiner's comments have been carefully considered. In response, the specification, Abstract and claims are amended, and remarks are set forth below in a sincere effort to place the present application in form for allowance. The amendments are supported by the application as originally filed. Therefore, no new matter is added.

OFFICE ACTION SUMMARY SHEET

In item 1 of the Office Action Summary (Form PTO-326), the Examiner states that the Office Action is responsive to a communication filed on July 11, 2002. According to the records of the undersigned, no papers were filed on July 11, 2002. It is respectfully requested that the Examiner correct this obvious error in the Form PTO-326.

The Form PTO-326 also refers to drawings filed on July 11, 2002 (see item 10). No drawings were filed on July 11, 2002. Correction is respectfully requested.

PRIORITY CLAIM

In the Office Action, the Examiner acknowledges applicants' claim of foreign priority but states that "applicant has not filed a certified copy of the corresponding Japanese application as required by 35 U.S.C. 119(b)".

A certified copy of the Japanese patent application upon which priority is claimed will be submitted subsequent to submission of this response.

DRAWINGS

In the Office Action, the drawings are objected to under 37 C.F.R. 1.83(a) as not showing every feature of the invention specified in the claims. Applicants address each of the items raised in the objection to the drawings in the order in which they were set forth in the Office Action.

(a) The "opening/closing" valve recited in claims 4 and 6 is described in the application as "flap valve 19" (see page 12, lines 8-9).

(b) The "hole diameter changeable member" recited in claim 18 is described in the application as "blade 95" (see page 28, line 3).

(c) The "second sealing portion" recited in claim 4 is described in the application as "sealing ring portion 28" (see page 14, line 11).

(d) The "housing" recited in claim 19 is the main body of the sheath tube that forms, for example, the tube passage 7 and the internal space 8 shown in Fig. 2. Specifically, it is described in the application as, for example, "main body section 15".

(e) The "port" recited in claim 19 is the passage formed by, for example, the large diameter hole 33 or the short diameter hole 34 shown in Fig. 3 of the application.

In view of the foregoing, reconsideration and withdrawal of the objection to the drawings under 37 C.F.R. 1.83(a) are respectfully requested.

ABSTRACT

In the Office Action, the Abstract was objected to as containing over 150 words and using technical legal phraseology. In response, the Abstract is amended in a sincere effort to obviate the objection thereto. In view of the amendment of the Abstract, reconsideration and withdrawal of the objection to the Abstract are respectfully requested.

SPECIFICATION

In the Office Action, the specification is objected to as failing to provide proper antecedent basis for the claimed subject matter.

Applicants respectfully address each of the objections in the order presented in the Office Action.

(f) The "opening/closing valve" recited in claim 2 corresponds to the flap valve 19 recited on page 12, lines 8-9.

(g) The "second sealing portion" referred to in claim 5 corresponds to the sealing ring portion 28 mentioned on page 14, line 11.

(h) The "hole diameter changeable member" in claim 18 corresponds to the blade 95 mentioned at page 28, line 3.

(i) The "housing" recited in claim 19 corresponds to main body section 15 and is the main body of the sheath tube that forms, for example, the tube passage 7 and the internal space shown in Fig. 2.

(j) The "port for introducing a surgical instrument" recited in claim 19 is the passage formed by, for example, large diameter hole 33 or short diameter hole 34 shown in Fig. 3.

With regard to the informalities on page 39, appropriate amendments to the detailed description at page 39, lines 22 and 25 have been made.

In view of the foregoing, reconsideration and withdrawal of the objection to the specification are respectfully requested.

CLAIM OBJECTIONS

In the Office Action, claims 1 and 18 are objected to because of informalities. In response, claims 1 and 18 are amended in a sincere effort to obviate the objections thereto.

REJECTION UNDER 35 U.S.C. 112, SECOND PARAGRAPH

In the Office Action, claims 4-6, 15, 20 and 23 are rejected under the second paragraph of 35 U.S.C. 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In

response, the claims are amended, where necessary, in a sincere effort to obviate the indefiniteness rejection.

With regard to the rejection of claim 11, claim 11 is amended as set forth hereinabove.

With regard to the rejection of claim 15, applicant respectfully states that it appears that the Examiner intended to reject claim 14 instead of claim 15. Accordingly, an appropriate amendment has been made to claim 14. If the applicants' understanding is not accurate, the Examiner is respectfully requested to point this out in the next Patent Office communication.

With regard to the rejection of claim 20, applicants respectfully point out to the Examiner that claim 20 is dependent on claim 19 and claim 19, in the second line thereof, recites "a housing" which provides proper antecedent basis for "the housing" in claim 20.

In view of the foregoing amendments and remarks, reconsideration and withdrawal of the rejection of the claims under the second paragraph of 35 U.S.C. 112 are respectfully requested.

PRIOR ART REJECTIONS

In the Office Action, claims 1-5, 8, 10, 15, 16, 18, 19, 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 5,792,113 (Kramer et al). Claims 6, 12-14 and 18 are rejected under 35 U.S.C. 103 as being unpatentable over Kramer

et al in view of USP 4,715,360 (Akui et al). Claims 7, 9, 11, 21 and 22 are rejected under 35 U.S.C. 103 as being unpatentable over Kramer et al in view of Akui et al, and further in view of USP 5,401,248 (Benchini).

In response, claims 1 and 19 are amended to include limitations from claims 2, 4 and 7. Specifically, claims 1 and 19 now recite that the sealing member has first, second and third sealing portions that (are integral with each other so as to) form one sealing member. The advantages of this structure are described in the present application at, for example, page 20, line 15 to page 22, line 7.

None of the references of record disclose, teach or suggest, when taken either alone or in combination, the trocar sheath tube as presently defined by amended claims 1 and 19 having the advantages set forth in the application.

In the Office Action, the Examiner states with respect to claim 4 that Kramer et al clearly illustrates two sealing portions in the drawing in Fig. 2. Applicants respectfully state that Kramer et al teach an outer seal 19 and inner seal 18 wherein the inner seal stretches to fit around the instrument, thus providing the requisite seal for the instrument having a specific diameter. The outer seal and inner seal recited in Kramer et al do not, however, correspond to the structure and function of the invention as set forth in the amended claims.

With regard to claim 7, the Examiner asserts that Akui et al teach a sealing member having two sealing portions when the first

sealing portion is distanced from the second sealing portion. However, limitations from claim 7, which have been included in claims 1 and 19, recite a third sealing portion spaced from the first sealing portion wherein the sealing portion seals a space between a medical instrument and the holding portion. Such structure is not disclosed, taught or suggested by Akui et al nor any of the other references of record.

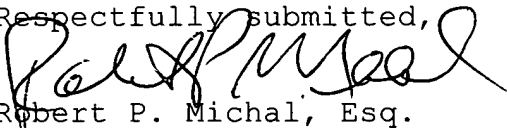
In view of the foregoing, independent claims 1 and 19 and claims 3, 5, 6, 8-18 and 20-23 which are dependent thereon are patentable over the cited references under 35 U.S.C. 102 as well as under 35 U.S.C. 103.

* * * * *

In view of the foregoing, entry of this Amendment, allowance of the claims and the passing of this application to issue are respectfully solicited.

If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

Respectfully submitted,


Robert P. Michal, Esq.
Reg. No. 35,614

Dated: January 30, 2003

Frishauf, Holtz, Goodman & Chick, P.C.
767 Third Avenue - 25th Floor
New York, New York 10017-2023
Tel. No. (212) 319-4900
Fax No. (212) 319-5101
RPM/sdf
sdf/c:\d:\00\00146.amd



VERSION MARKED TO SHOW CHANGES MADE

2,47 non

1. (Amended) A trocar sheath tube comprising:

an insert portion introduced into the inside of a body, the insert portion having a tube passage, the tube passage being capable of passing a medical instrument internally, the insert portion guiding the medical instrument into the inside of a body through [this] the tube passage;

a holding portion provided at the proximal end side of the insert portion in order to hold the proximal end side of the medical instrument inserted through the insert portion, the holding portion having an opening communicating with the tube passage of the insert portion;

a sealing member removably mounted to the opening of the holding portion, the sealing member having a first sealing portion coming into intimate contact with the medical instrument, the sealing member sealing a space between the medical instrument and the holding portion by this first sealing portion; and

a fixing member removably mounted to the sealing member, the fixing member [adopted] adapted to fix the sealing member to the holding portion[.];

wherein an opening/closing valve for openably closing the opening of the holding portion is provided in the holding portion;

wherein the sealing member has a second sealing portion which abuts with an opening/closing valve in a sealed state and

25 closes the opening of the holding portion in cooperation with the
opening/closing valve; and

wherein the sealing member has a third sealing portion
positioned to be spaced from the first sealing portion, the third
sealing portion sealing a space between the medical instrument
30 and the holding portion in intimate contact with the medical
instrument.

5 5. (Amended) A trocar sheath tube according to
claim [4] 1, wherein the opening/closing valve is a flap valve
movable between a first position where the valve abuts with a
second sealing portion and a second position where the valve is
spaced from the second sealing portion.

8. (Amended) A trocar sheath tube according to
claim [7] 1, wherein the first and third sealing portions have
holes through which the medical instruments can be inserted,
respectively, and the hole diameter of the first sealing portion
5 and that of the third sealing portion are differ from each other.

11. (Amended) A trocar sheath tube according to claim 1,
wherein the sealing member is deformed by [pushing force using]
the fixing member when the fixing member contacts the sealing
member.

12. (Amended) A trocar sheath tube according to claim [7] 1, wherein the sealing member has an arm portion for causing the first and third sealing portions to be coupled with each other.

14. (Amended) A trocar sheath tube according to claim 12, wherein the arm portion biases the third sealing portion toward a first position where the third sealing portion is arranged coaxially with the first sealing portion or toward a second
5 portion where the third sealing portion is distant from the first sealing portion by 180 degrees [and] or over.

17. (Amended) A trocar sheath tube according to claim [2] 1, wherein the sealing member serves as the opening/closing valve.

18. (Amended) A trocar sheath tube according to claim [2] 1, wherein the first sealing portion of the sealing member has a [hold] hole through which the medical instrument can be inserted, and the diameter of the [hold] hole is changed by a
5 hole diameter changeable member to be abutted with the sealing member.

19. (Amended) A trocar sheath tube comprising:
a housing having a space therein;

a port for introducing a surgical instrument into the space of the housing;

5 an elongated insert portion having a tube passage communicating with the space of the housing;

a sealing means for closing the port in a sealed state; and

a fixing member for fixing the sealing means via a hinge,
10 wherein the sealing means [can be] is removably mounted to the housing and the fixing member is tunably mounted to the housing,

wherein the sealing means includes a first sealing portion coming into intimate contact with the surgical instrument, the
15 sealing member sealing a space proximate the surgical instrument and a holding portion by this first sealing portion,

wherein an opening/closing valve for openably closing an opening of the holding portion is provided in the holding
portion,

20 wherein the sealing member has a second sealing portion which abuts with the opening/closing valve in a sealed state and closes the opening of the holding portion in cooperation with the opening/closing valve; and

wherein the sealing member has a third sealing portion
25 spaced from the first sealing portion, the third sealing portion sealing a space between the surgical instrument and the holding portion in intimate contact with the medical instrument.

23. (Amended) A trocar sheath tube according to claim 19,
wherein a shoulder portion meshed with the fixing member is
provided [in the vicinity of] on the periphery of the sealing
means.

VERSION MARKED TO SHOW
- 39 - CHANGES MADE

deformed button portion 232, a pair of claws 233 provided on both sides of the deformed button portion 232, and a pair of thin wall portions 236 provided in the vicinity of the each claw 233. A pair of claws 233
5 are fitted into a groove 235 (refer to FIG. 26) inside of a pair of hangover portions 234 provided at the proximal end of the seal receiving portion 224 of the cover section 216 (refer to FIG. 26). FIG. 27B shows a state in which the deformed button portion 232 is held
10 down. In this state, a pair of thin wall portions 236 of the deformed ring 230 is deformed, the upper part of the deformed ring 230 moves downward, and a pair of claws 233 are released from grooves 235 of a pair of hangover portions 234.

15 As shown in FIG. 25, the sealing member 226 consists of an elastic material. The sealing member is composed of a mounting portion 237 attached to the seal receiving portion 224; a main opening portion 238 present at its center of the mounting portion 237; an
20 arm portion 239; and a subsidiary opening portion 240 present at the end of the arm portion 239. The arm portion 239 overhangs [overhung] on the side of the mounting portion 237 and then extends in the obliquely backward direction. A positioning shoulder portion 242
25 is provided over the full [the] periphery of the mounting portion 237. When the sealing member 226 is sandwiched between the seal receiving portion 224 and the seal

09/521,367
Att Unit: 3731

fixing portion 225, the opening 208 of the holding portion 203; and an opening 241 of the seal fixing portion 225 and an opening 247 of the sealing member 226 are coaxial with each other by means of the positioning shoulder portion 242. Then, a cylinder portion 245 at the rear end of the seal fixing member 225 is fitted with a recess portion 244 formed between the shoulder portion 242 and a side wall 243 of the main opening portion 238. A sealing lip (a second sealing portion) 260 is provided at the end of the side wall 243 of the main opening portion 238. The sealing lip 260 abuts with the flap valve 219 in sealed state, and closes the opening 208 of the holding portion 203 in cooperation with the flap valve 219. In addition, a conical sealing film (a first sealing portion) 246 is provided at the main opening portion 238, and the opening 247 is present at its center of the sealing film 246. A thin film portion (a third sealing portion) 248 is provided at the subsidiary opening portion 240, and a small opening 249 with its internal diameter smaller than the opening 247 is provided at its center of the thin film portion 248. The sealing member 226 may be a duck bill valve or a slit valve.

As shown in FIGS. 28 and 29, a pair of cam arms 250 extend from the tip end face of the cover section 216. A cam protrusion 251 protruding outwardly is provided at its tip end of each cam arm 250. A pair of

09/521,367
Art Unit: 3731

ABSTRACT OF THE DISCLOSURE

A trocar sheath tube [according to the present invention comprises] ^{includes} an insert portion introduced into the inside of a body, ^{The} the insert portion ^{has} having a tube passage, ^{The} the tube passage ^{enables internal passage of} [being capable of passing] a medical instrument [internally, the insert portion ^{body} guiding] ^{and guides} the medical instrument into the inside of a ^{body} through this tube passage, ^A a holding portion ^{is} provided at the proximal end side of the insert portion in order to hold the proximal end side of the medical instrument inserted through the insert portion, ^{The} the holding portion ^{has} having an opening communicating with the tube passage of the insert portion, ^A a sealing member ^{is} removably mounted to the opening of the holding portion, ^{and has} [the sealing member having] a first sealing portion [∧] [coming into] intimate contact with the medical instrument, ^{The} the sealing member ^{seals} [sealing] a space between the medical instrument and the holding portion by [this] ^{the} first sealing portion, and ^A a fixing member [adopted to fix] ^{fixes} the sealing member to the holding portion.

09/521,367
Art Unit: 3731